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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,475	12/31/2003	Sreedhara Alavattam	13447	9857

24116 7590 08/25/2005

BATTELLE MEMORIAL INSTITUTE
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EXAMINER

ROY, GARGI

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/750,475

Applicant(s)

ALAVATTAM ET AL.

Examiner

Gargi Roy

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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Claims 1-28 are pending and are under examination.

Priority is set to December 31, 2002 based on the filing date of the provisional application with serial no. 60/437,351.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3–4, 11, 12-20, 22,25-28 are rejected under 35 U.S.C. 102 (b) as being anticipated by Zhu *et al.* (*Nat. Biotechnol.* **18**, 52-57 (2000)).

Zhu *et. al.* made millicylinders (i.e., microparticles) comprising of bFGF, heparin, Mg(OH)₂, BSA and polylactic and glycolic acids (poly(D, L, lactide coglycolide) (PLGAs) (pg 55, left column, paragraph 1)

and bFGF (Mg(OH)₂, BSA and PLGAs (pg 55, left column, paragraphs 1 and 2)

and bFGF Arabic gum and PLGAs (pg 55, left column, paragraphs 2).

Therefore, Zhu *et. al* teach a controlled formulation comprising a protein (bFGF), a polysaccharide stabilizer (Arabic gum), encapsulated in a biodegradable polymer (**claims 1,11**) comprising heteropolymers comprising lactic and glycolic acids (**claims 3,4**).

The ratio of heparin stabilizer to bFGF protein was 1:1 (pg 55, left column, paragraph 1) (**claims 25-28**).

For BSA at 14.4% to bFGF and bFGF at 0.0025% (legend Fig 3), the stabilizer to bFGF protein was 5760:1 (**claims 26-28**).

Claims 1-14, 16-20, 21, 22-28 are rejected 35 U.S.C. 102 (b) as being anticipated by Morlock *et. al.* (*J. Control Release*. 1998: **56**: 105-115).

Morlock *et.al.* prepared EPO microspheres (microparticles) in combination with protein stabilizer, BSA by mixing in an organic phase containing Poly(D,L-lactic-co-glycolic) acid polymers followed by an addition to a polyvinylalcohol solution and a final step of lyophilization of the entire above mixture (pg 107, right column, paragraphs 1 and 2).

Therefore, Morlock *et.al.* teach a preparation of microspheres comprising a protein (EPO), a protein stabilizer (BSA) (**claim 16**) in combination with a commonly used anionic surfactant (Polyvinylalcohol) (Wakeman *et. al. J. Membrane. Sci.* 1995; **106**: 57-65) (**claim 5**), emulsified with Poly(D,L-lactic-co-glycolic) acid polymers (**claims 2,12, 21, 22**) dissolved in organic solvent such as Dichloromethane (DCM) (**claims 23, 24**) followed by lyophilization (**claim 13**).

Double Patenting

Claims 12 and 14 -15 rejected under the judicially created doctrine of double patenting over claims 12-18 of U. S. Patent No. 6896894 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, such as, use of polysachharide gum selected from a group of gum arabic, xanthan gum, locust bean gum, tragacanth gum, gum karaya and gum ghatti as a protein stabilizer in a controlled release formulation.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 13, 17, 18, 22, 24 and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2 there is no antecedent basis for surfactant in claim 1.

In claim 13, the terms "other methods" are indefinite in defining a method to create particles from solutions.

Claims 17 and 18 are dependent on claim 2, not 12. Also, in claims 17-20 there is no antecedent basis for polymers in claim 12.

In claim 24, there is no antecedent basis for an organic solvent in claim 22.

In claim 22 the terms "providing a source of protein (a) and stabilizer (b)" are vague and indefinite in reciting a protein or a stabilizer or their source. It is incomprehensive to determine the ratio of the stabilizer to protein with an imaginary protein and stabilizer as claimed in claim 22 (c).

In Claims 25-28 the term "about" is used to represent a numerical ratio. This term is indefinite in teaching the ratios of various ingredients for the composition of the sustained release formulation.

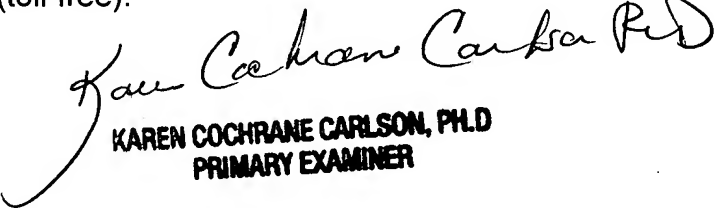
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gargi Roy whose telephone number is 571-272-1306. The examiner can normally be reached on 8:30 am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER